

REMARKS

Claim 21 and 23-29 were pending. No claim is allowed.

Summary of Examiner Interview

Applicants gratefully acknowledge Examiner Bunner's time and willingness to discuss the outstanding utility rejection. The standard employed by the Examiner was discussed as well as the basis for that standard.

Rejection Under 35 U.S.C. §101 and § 112, first paragraph

Claims 21 and 23-29 remain rejected under 35 U.S.C. § 101 and § 112, first paragraph as allegedly lacking a credible, specific, or substantial asserted utility or a well established utility for reasons of record. Briefly, the Examiner remains steadfast in her assertion that a precise function is required of a protein and should be "empirically determined". According to the Examiner, a specific role or function for FDF03 is lacking in the specification. The Examiner maintains that the biological role of FDF03 protein and its significance has not been disclosed in the specification. The Examiner also asserts that definitive differential cell expression of FDF03 was not taught in the specification. Applicants traverse this rejection for reasons of record as well as those discussed below.

As a preliminary matter, Applicants note that the Examiner appears to be relying heavily on *In re Fisher*, a case whose facts are easily distinguishable from the current application. 421 F.3d 1365 (2005). Briefly, the claimed invention in *Fisher* relates to expressed sequence tags or ESTs from maize plants. Following a rejection by the Board of Patent Appeals and Interferences for lack of utility, the court affirmed the Board's findings. In brief, the specification asserted a number of uses for the ESTs, but failed to provide data in the specification *or during prosecution* relating to the asserted utilities. The court found that the claimed ESTs were mere research intermediates because the applicant failed to provide a function for the underlying gene. In particular, the court noted that during the entirety of the prosecution and trial *no evidence* was presented to support any of the alleged functions. *Fisher*, 421 F.3d at 1377 ("[The applicant] disclosed a variety of asserted uses for the claimed ESTs, but failed to present any evidence -- test data, declaration, deposition

testimony, or otherwise -- to support those uses as presently beneficial and hence practical.”) In other words, the presence of data that supported the asserted utilities either in the specification or in post-filing submissions would have been sufficient to meet the relatively low standard set for utility under 35 U.S.C. § 101.

The specification meets the standard discussed in *Fisher* by disclosing more than merely a generic utility for FDF03 as well as providing evidence that the asserted utilities are significant and have a presently available benefit to the public. As previously discussed, the specification disclosed that the FDF03 protein “likely plays a role in regulation or development of hematopoietic cells, ... *e.g.*, antigen presentation and the resulting effector functions.” See the specification at page 68, line 37 to page 69, line 3. The evidence demonstrates that FDF03 does indeed play a role in the regulation in mast cells and antigen presenting cells. The specification further discloses FDF03 as a cell surface marker that is discretely and specifically expressed on cells of the myelomonocytic lineage, *e.g.*, monocytes. See the specification at *e.g.*, page 54, lines 18-22 and page 87, line 35 to page 88, line 6. These are specific and substantial utilities that are supported by copious evidence already of record. The evidence shows that the asserted utilities were accurate as disclosed in the specification and immediately useful. The very specific, disclosed utilities cannot be construed as being generic or without immediate benefit to the public as such a use cannot be assigned to just any new protein or even any new protein expressed on antigen presenting cells. Moreover, the evidence demonstrates that FDF03 has immediate benefit in its regulation of at least two different types of hematopoietic cells. That alone is sufficient to meet the utility requirement.

Applicants again submit that there is no legal requirement for empirical evaluation or that a certain level of specificity regarding the role or function of a protein must be achieved. Applicants strongly disagree with the assertion that the biological role of FDF03 was not disclosed for reasons already of record. Quite simply, there is no requirement for definitive evidence and disclosure of a detailed biologic profile for a protein to satisfy the utility requirement. The utility must *merely* be capable of providing some identifiable benefit. Any of the utilities disclosed for FDF03 satisfies this standard.

Finally, Applicants agree that *Ex parte Hedrick* is not binding precedent on the Office. However, it was offered merely to illustrate the standard as employed by the Board in recent cases concerning utility standards and related rejections.

As the specification provides adequate utility for the reasons discussed above, Applicants submit that the specification also provides sufficient written description on how to use the claimed FDF03 polypeptide.

For at least these reasons, Applicants respectfully submit that the rejection under 35 U.S.C. §§ 101 and 112 are overcome and should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **140942001311**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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